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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,316	07/18/2003	Cheng Shu Chaw	6565-66400-01	4339

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
03/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,316	CHAW ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-28* is/are pending in the application.

4a) Of the above claim(s) *9 and 20-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-8 and 10-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/19/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/30/2008 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,5-8,10-13,15-16 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Roorda et al. (US5,543,156),

Roorda teaches bioerodible devices comprised of a) bioerodible polymer such PGLA (including a 50:50 mixture of lactic and glycolic acids, MW 30,000), poly(orthoesters), polyesters, polyanhydrides and mixtures and combinations of the above polymers b) an active agent including scopolamine (a known anti-cholinergic agent) in combination with eserine salicylate (same as physotigmine). See abstract, col 4 lin 7-12, col 6 lin 60-63, examples and claims 1-2. The devices could be manufactured

by standard techniques to form microparticles and the devices could be placed on or in the wounds of an animal by injecting the microparticles. See col 7 lin 31-59. Regarding claim 18 from the figures and examples several of the compositions of Roorda continued to release the active after one week, thus the limitation is met. Furthermore even if the compositions disclosed as having the release rates did not contain all of applicants claimed ingredients, such as the active, it is still inherent that since Roorda teaches the exact same microparticle composition as claimed by applicants the release rate will be the same.

Response to Arguments

Applicant's arguments filed 01/03/2008 have been fully considered but they are not persuasive.

Applicants assert Roorda discloses a broad genus of potential applications and thus is not sufficient for the purposes of inherent anticipation because disclosure of a genus does not inherently disclose all species of that broad category. Applicants assert that the recitation of mixtures and combinations of the polymers is a broad genus of possible combinations of a list of individual polymers and several combinations of the polymers would have equivalent hydrophobicties. Applicants also assert that Roorda only actually describes one specific combination of polymer A and B which are poly(orthoester)s which would have the same hydrophobicity. Applicants thus surmise that their claimed polymer mixture where one polymer is more hydrophobic then the other does not necessarily result from the teachings of Roorda. Applicants lastly surmise that there is no direction within Roorda to select polymers having varying

degrees of hydrophobicity and there is no disclosure that including a more hydrophobic polymer would dampen the sustained release of an active carbamate.

The relevance of these assertions is unclear. Firstly applicant's claimed invention is to a microparticle or a formulation comprising the microparticle, as long as the cited prior art teaches all of the claimed ingredients within the microparticle/formulation it anticipates applicants claimed invention. Applicant's claims are not drawn to an abstract idea and/or method of selecting polymers based on their hydrophobicties; applicants have not set forth in the present amendment any patentable distinction from the Roorda reference because the formulations have the same scope. The intended use type of limitation that the release of carbamate is dampened or slowed is an inherent property of the microparticle, since as recited above Roorda teaches the same microparticle as applicants claimed invention the release rate of the active will be controlled in the same manner. Roorda's disclosure recites the use of polymer mixtures that includes only the following species PLA, PGA, PLGA, polyamides, polyesters, polyorthoesters, polyanhydrides and PVP. The only species from the above recitation that would be excluded by applicant's dependent claims for the first and second polymer are PVP and polyamides. Furthermore the claims recite that mixtures of biodegradable polymers (claim 1) can be used and a latter dependent claim (claim 2) poly(orthoesters) and PLA,PGA, PGLA are recited as the biodegradable polymers. Thus contrary to applicants assertion the specific polymer mixtures of Roorda are well defined and not overly broad or essentially teaching a genus or selected arbitrarily from a long list. Therefore by the above reasoning set forth by the examiner Roorda does teach and

even claims the same polymer mixture as applicants claimed invention. Regarding applicants assertion that Roorda actually only discloses one mixture of two poly(orthoester)s, the examiner disagrees, the discussion of polymers A and B was just one embodiment of an alternative polymer mixture and was not intended to be limiting in any manner to the scope of Roorda's invention. The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-3, 5-8 and 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al. (US5,543,156).

Roorda is disclosed above. Roorda discloses all of applicants claimed invention but is silent on the specific amount of physotigmine. However, Roorda discloses that the amount of active agent employed in the delivery device will be that amount necessary to deliver a therapeutically effective amount of the agent to achieve the desired result at the site of application. In practice, this will vary depending upon the particular agent, the severity of the condition, and the desired effect, as well as the desired rate and duration of release. Thus from the disclosure of Roorda it would have been obvious to one of ordinary skill in the art at the time of applicants claimed invention to optimize the amount of physotigmine in the microparticle because it was already well known that the amount of therapeutic would vary depending on the desired effect and the severity of the condition and thus could be obtained through normal and routine experimentation. It also would be obvious to one of ordinary skill in the art to use the amounts of active that were disclosed as useful in the experimental sections of Roorda. In the experimental section the drug loading concentration was 5 and 10% by weight, thus one of ordinary skill could envision that the bioactive physotigmine could be used in amounts of 10% and have a reasonable expectation of success since other actives were used in the same amount within the patents examples.

Response to Arguments

Applicant's arguments filed 01/03/2008 have been fully considered but they are not persuasive.

Applicants assert as stated above that Roorda does not teach or suggest a microparticle comprising a mixture of biodegradable polymer wherein one polymer is more hydrophobic than the other and such mixture dampens or slows the initial release of carbamate. Applicants further assert that as stated above Roorda describes a broad genus of possible polymer combinations and therefore does not necessarily fall within the scope of the claimed polymer combination. Applicants assert that the release rate of the described device within Roorda is primarily independent of the rate of erosion of the polymer matrix and depends upon the amount of excipients and thus teaches away from their presently claimed invention.

The remarks above for why Roorda discloses a narrow enough species of polymers to read on applicants claims are incorporated herein. The remarks above for why Roorda teaches applicants claimed polymer mixture and how that mixture controls the release rate is also incorporated herein. Regarding applicants assertion that Roorda teaches away from their claimed invention because the release rate of the microparticle was said to be dependent on the amount of excipients, the relevance of this assertion is unclear. Regardless of what Roorda discloses as controlling the release rate of the active the microparticles the particles are still the same as applicants claimed invention. Thus even if Roorda is silent on how the polymer controls the release of active the same composition will inherently have the same properties including the effects of the polymer mixture on the release of drug. It appears as though applicants are claiming a new or undiscovered property of an old combination. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are

produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/622,316	CHAW ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	